

AMENDMENT

Please amend the claims as follows:

B1 Sub 1 1. (Amended) A therapeutic agent for treatment of acute lung injury resulting from indirect causes which occur systemically and thereby injure the lung indirectly comprising anti-IL-8 antibody as an active ingredient in an amount effective to treat the acute lung injury.

B2 Sub 2 16. (Amended) A process for the production of a therapeutic agent for treatment of acute lung injury resulting from indirect causes which occur systemically and thereby injure the lung indirectly comprising mixing anti-IL-8 antibody in an amount effective to treat the acute lung injury with an pharmaceutical acceptable carrier.

B3 Sub 3 31. (Amended) A therapeutic method for treatment of acute lung injury resulting from indirect causes which occur systemically and thereby injure the lung indirectly, which method comprises administering anti-IL-8 antibody to a subject in need of said therapy.

34. (Amended) The method according to any one of claims 31, 32, and 33, in which the indirect cause is the sepsis syndrome.

B4 35. (Amended) The method according to any one of claims 31, 32, and 33, in which the indirect cause is severe nonthoracic trauma.

36. (Amended) The method according to any one of claims 31, 32, and 33, in which the indirect cause is hypertransfusion during emergency resuscitation.

37. (Amended) The method according to any one of claims 31, 32, and 33, in which the indirect cause is an artificial cardiopulmonary bypass surgery.

REMARKS

Reconsideration is respectfully requested in light of the foregoing amendments and the remarks which follow.

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Claims 1-29 and 31-44 are before the Examiner. Claims 34-37 are amended to correct certain informalities in the manner suggested by the Examiner. Claims 1, 16 and 31 are amended to more clearly distinguish over the applied art. Support for the amendments to claims 1, 16 and 31 are found on page 29, starting at line 35, and including page 31, lines 33-34 of the specification, as well as page 32, line 24, Example 1 (pages 36-37). No new matter is believed to have been introduced by these amendments.

Acknowledgement of receipt of the priority document and the claim for priority is noted with appreciation, as is the return of the initialed PTO-1449 forms.

Objections under 37 CFR 1.75

Claims 1-8, 17-22 and 34-37 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must depend from one or more previous claims in the alternative form only.

The cancellation of claims 1-8, 17-22 and the suggested amendments to claims 34-37 render the objection moot.

Rejections under 35 USC 102

Claims 1-29 and 31-44 are rejected under 35 USC 102(a) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Folkesson *et al.*

The claims have been amended to avoid the teachings of Folkesson *et al.* The patient treated has acute lung injury resulting from indirect causes which occur systemically.

The applied reference, Folkesson, E.G., *et al.*, refers to *direct* injury of the lung caused by acid aspiration. It is well recognized and accepted in the art that *indirect* injury to the lung and *direct* injury thereof are completely different. For example, according to the Conference Report of The American-European Consensus Conference on ARDS (Bernard, G. R., *et al.*, *Am J Respir Crit Care Med* (1994) 149:818-824) (see, page 3, lines 15-20 of the specification), ARDS and ALI are categorized on the basis of their causes of "direct injury" and "indirect injury," respectively (see, page 821, left column, bottom portion to the right column, top portion).

Please note that an effect or action of a drug to the *direct* injury and an effect or action of the same drug to the *indirect* injury are completely different. For example, Nishina, K. *et al.*, *Anesthesiology* (1998) 88:1300-1309 (Abstract enclosed), describes administration of Lidocaine to a direct injury caused by acid aspiration as being effective. On the other hand, K. Nishina *et*

al. Anesthesiology (1995) 83:169-177 (enclosed) describes administration of Lidocaine to indirect injury caused by endotoxin infusion as not being significantly effective.

Accordingly, even though the cited Folkesson *et al.* reference shows that anti-IL-8 antibody is effective against direct injury, this fact does not suggest that the anti-IL-8 antibody is effective against indirect injury. Therefore, the present invention of the amended claims should be patentable over the citation. The claims have been amended to make this distinction clear.

Since the reference no longer teaches each and every element of the claims, withdrawal of the rejection is respectfully requested.

Conclusion

Having addressed all the rejections and objections, the application is believed to be in condition for allowance. A notice to that effect is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 350292000500. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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